

USSN10/672,936, filed September 25, 2003  
Attorney Docket No. 1103326-0502 CON  
Page 3 of 7

## **REMARKS**

### **I. Petition for Extension of Time**

Applicants herewith petition the Commissioner for Patents to extend the time for response to the Office action mailed April 29, 2005 for three months from July 29, 2005 to October 29, 2005. Authorization is given to charge the extension of time fee of \$1,020.00 (37 C.F.R. §§1.136 and 1.17) to Deposit Account No. 23-1703. Any deficiency or overpayment should be charged or credited to the above numbered deposit account.

### **II. Claim Rejection – 35 U.S.C. §112**

Claim 18 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. It is alleged that the expression “gastric acid related condition” is indefinite.

Claim 18 has been amended to recite that the claimed method is directed to the inhibition of gastric acid secretion. Support is found at page 6, line 1, of the specification.

Applicants submits that no new matter has been introduced by the claim amendment and that the §112 rejection is moot in view of the claim amendment. Withdrawal of the rejection is requested.

### **III. Claim Rejections – Double Patenting**

Claims 1, 2, 14 and 18 are rejected under 35 U.S.C. §101 as claiming the same invention as that of claims 1, 2, 11 and 12 of US 6,369,085 (the “085 patent”). In the Office Action, the Examiner states:

- the scope of pending claims 1, 2, 14 and 18 is not different from the scope of claims 1, 2, 11 and 12 of the '085 patent;
- applicants have not provided any reasons why the scope is different; and
- it is a question whether the major peaks in the X-ray diffractogram of the compound of claims 1, 2, 14 and 18 are different from the major peaks in the X-ray diffractogram of the compound of claims 1, 2, 11 and 12 of the '085 patent are different.

USSN10/6/2,936, filed September 25, 2003  
Attorney Docket No. 1103326-0502 CON  
Page 4 of 7

The Examiner's attention is respectfully directed to M.P.E.P. §804(II)(A) for a discussion of the requirements of a statutory double patenting rejection where it is stated that:

## **II. REQUIREMENTS OF A DOUBLE PATENTING REJECTIONS (INCLUDING PROVISIONAL REJECTIONS)**

### **A. STATUTORY DOUBLE PATENTING – 35 U.S.C. §101**

A reliable test for double patenting under 35 U.S.C. 101 is whether a claim in the application could be literally infringed without literally infringing a corresponding claim in the patent. *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970). Is there an embodiment of the invention that falls within the scope of one claim, but not the other? If there is such an embodiment, then identical subject matter is not defined by both claims and statutory double patenting would not exist.

Claims 1, 2, 14 and 18 of the subject application and claims 1, 2, 11 and 12 of the '085 patent are related as genus and species, respectively. Consequently, there is no identity of invention within the meaning of §101 and the *Vogel* test. Accordingly, withdrawal of the §101 rejection is requested.

## **IV. Claim Rejections – 35 U.S.C. §103**

Claims 1, 2, 14, 17 and 18 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindberg (WO 94/27988) and Bergstrand (WO 96/01623).

The Examiner states that Lindberg, at Example 5 on page 12, and Bergstrand, at Example A on page 34, disclose the magnesium salt of S-omeprazole. The Examiner acknowledges, however, that neither Lindberg nor Bergstrand discloses or suggests the trihydrate of the magnesium salt of S-omeprazole. Therefore, in the absence of some unexpected superior property, the Examiner concludes that the claimed invention would have been obvious to the person of ordinary skill in the art.

### **A. The prior art does not suggest the desirability of the claimed trihydrate form.**

At the time the claimed invention was made, it was not known that the magnesium salt of the (-)-enantiomer of omeprazole occurred in structurally different forms. This assertion is

USSN10/672,936, filed September 25, 2003  
Attorney Docket No. 1103326-0502 CON  
Page 5 of 7

consistent with the acknowledged failure of Lindberg and Bergstrand to disclose or suggest the claimed trihydrate form, and with Applicants' statement appearing at page 3, lines 3-4 of the specification:

It has been surprisingly found that the magnesium salt of S-omeprazole occurs in a number of structurally different forms.

In the absence of such knowledge or suggestion, Applicants respectfully challenge the Examiner's contention, as stated on page 3 of the *nonfinal* Office Action mailed July 16, 2004, that it would have been obvious to one skilled in the art "to prepare hydrates of magnesium salt (*sic*) of S-omeprazole".

Applicants rely on Section 2143.01 of the Manual of Patent Examining Procedure (M.P.E.P.) which provides that:

**2143.01 Suggestion or Motivation to Modify the References**

**THE PRIOR ART MUST SUGGEST THE  
DESIRABILITY OF THE CLAIMED INVENTION**

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention *where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art.*

(Emphasis added)

Comparative Examples 5 and 6 at pages 13-16 of the specification indicate that the dihydrate of S-omeprazole magnesium salt was known at the time the claimed invention was made. The product of Reference Example A at pages 17-18 is also S-omeprazole magnesium salt dihydrate. This Reference Example A is the same Example A appearing on page 34 of the cited reference to Bergstrand. Applicants submit that the dihydrate products of Examples 5, 6 and A, including the X-ray powder diffractograms depicted in Figures 3-5, respectively, do not teach, suggest or motivate to produce the claimed S-omeprazole magnesium salt trihydrate.

Absent any such teaching, suggestion or motivation by the prior art, §Section 2143.01 of the M.P.E.P. further provides that *prima facie* obviousness cannot be established simply because the claimed invention is within the capabilities of the skilled artisan or, as the Examiner has

USSN10/672,936, filed September 25, 2003  
Attorney Docket No. 1103326-0502 CON  
Page 6 of 7

stated, that it would have been obvious to one skilled in the art "to prepare hydrates of magnesium salt (*sic*) of S-omeprazole":

**2143.01 Suggestion or Motivation to Modify the References**

FACT THAT THE CLAIMED INVENTION IS WITHIN  
THE CAPABILITIES OF ONE OF ORDINARY SKILL  
IN THE ART IS NOT SUFFICIENT BY ITSELF  
TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

....*In re Kotza*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention)...

The Examiner has acknowledged that neither Lindberg nor Bergstrand discloses or suggests the trihydrate form. Notwithstanding the failure of the prior art to teach, suggest or motivate, the Examiner nevertheless concludes that it would have been obvious, i.e., within the capabilities of the skilled artisan, to make the claimed invention. This conclusion is contrary to the above-quoted sections of §2143.01 of the M.P.E.P. and the relevant case law. At the time the claimed invention was made, it was not known that the magnesium salt of S-omeprazole occurs in a number of structurally different forms. Absent this "specific understanding within the knowledge of a skilled artisan", the person of ordinary skill in the art would not have been motivated to look for another form of the magnesium salt of S-omeprazole. *In re Kotza, supra*.

**B. The claimed invention provides a greater than expected result.**

As stated above, the dihydrate of S-omeprazole magnesium salt was known at the time the claimed invention was made. With respect to the cited prior art, the product of Example A of the cited reference to Bergstrand is S-omeprazole magnesium salt dihydrate. Neither Lindberg nor Bergstrand suggests that the magnesium salt of the (-)-enantiomer of omeprazole could exist in another more advantageous form, e.g., in the form of a trihydrate. Furthermore, neither Lindberg nor Bergstrand suggests that the claimed magnesium salt of S-omeprazole trihydrate is more stable than the corresponding magnesium salt compounds of the prior art.

USSN10/672,936, filed September 25, 2003  
Attorney Docket No. 1103326-0502 CON  
Page 7 of 7

The improved physical and chemical properties that characterize the claimed compound is not suggested by the cited prior art. The demonstrated improvement in stability represents a greater than expected result. It is precisely this type of "greater than expected result" which has long been an evidentiary factor pertinent to a finding of nonobviousness. *United States v. Adams*, 383 U.S. 39, 51-52 (1966).


In conclusion, §2143.01 of the M.P.E.P., the relevant case law and the comparative data dictate the withdrawal of the §103 rejections.

### CONCLUSION

Applicants submit that pending claims 1, 2, 14, 17 and 18 are in condition for allowance, which action is earnestly solicited. The Assistant Commissioner is hereby authorized to charge Deposit Account No. 23-1703 in the event that any fee is required in connection with this communication.

Dated: October 28, 2005

Respectfully submitted,



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Attachment: Request for Continued Examination (Form PTO/SB/30)